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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/607,836

06/27/2003

Vinayak D. Bhat

020460-001691US

8416

60168

7590

10/10/2006

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EXAMINER

IZQUIERDO, DAVID A

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/607,836	BHAT ET AL.	
	Examiner	Art Unit	
	David A. Izquierdo	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-7,12,14,20-23,25,28,37 and 39-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,12,14,20-23,25,28,37 and 39-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1 and 20 have been considered but are moot in view of the new ground(s) of rejection. Applicant has agreed with Examiner's characterization of the Sirhan '375 patent and disagreed with the combination of Sirhan '375 and Toner '039, stating that Toner '039 fails to suggest the use pimecrolimus with a rate-controlling element. While it could be argued that this relationship is, in fact, taught by Toner '039 Verlee '081 has been provided to further teach the use of pimecrolimus in combination with a rate-controlling element

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 2, 4-7, 12, 14, 20-23, 25, 28, 37, and 39-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. (U.S. Patent Number 6,939,375) in view of Verlee et al. (U.S. Patent Application Publication Number 2004/185081). Sirhan et al. discloses an apparatus and method for controlled substance delivery comprising:

- An expandable stent structure with at least one source of at least one therapeutic capable agent and a rate controlling element covering a portion of the source (col. 3, lines 60-67; col. 5, lines 46-48).

- The release of at least one therapeutic agent capable of inhibiting restenosis (col. 3, lines 15-20).
4. however Sirhan et al. fails to specifically disclose the use of pimecrolimus as the therapeutic capable agent and the use of parylene as a rate controlling element. Verlee et al. teaches both the use of pimecrolimus as a therapeutic capable agent for inhibition of restenosis (paragraph 0138) and the use of a rate controlling element (paragraph 0061, line 16). It would have been obvious to one of ordinary skill in the art to combine the teaching of pimecrolimus with a rate-controlling element, as taught by Verlee et al., to a medical apparatus as per Sirhan et al, the motivation to combine being that pimecrolimus aides in the inhibition of restenosis and a rate controlling element controls the release of beneficial agents, thereby allowing for more controlled treatment of affected tissue.
5. **NOTE: The current Application claims benefit to Parent Application filed prior to the effective file date of Sirhan et al (2/13/01) but a review of the Parent Applications shows the currently claimed subject matter only receives the benefit to Provisional Application 60/472,536 (05/21/03).**

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
7. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

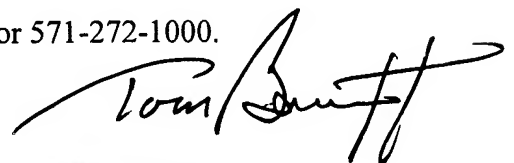
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Izquierdo whose telephone number is 571-272-1943.

The examiner can normally be reached on Monday through Friday from 8:00 am until 4:30 pm.

9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David A. Izquierdo



TOM BARRETT
PRIMARY EXAMINER
TECHNOLOGY CENTER 3700